UNITED STATES PATENT APPLICATION FOR GRANT OF LETTERS PATENT

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Method and System of Respiratory Therapy Employing Heart Rate Variability Coherence

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Related Patent Filings:

Method and System for Consciously Synchronizing the Breathing Cycle with the Natural Heart Rate Cycle (10/699,025), System and Method for Synchronizing the Heart Rate Variability Cycle With The Breathing Cycle (February 19, 2004), Method of Presenting Audible and Visual Cues for Synchronizing the Breathing Cycle With An External Timing Reference for Purposes of Synchronizing The Heart Rate Variability Cycle With The Breathing Cycle (March 15, 2004), Method and System Providing A Fundamental Musical Interval for Heart Rate Variability Synchronization (March 23, 2004)

Field of the Invention

The present invention relates to the field of medicine and in particular to the field of respiratory therapy. More particularly, it relates to the field of respiratory therapy wherein a human subject breathes air or other gases that are enriched with oxygen or other additives for the purpose of regaining, sustaining, or enhancing health.

Background of the Invention

A primary aspect of the field of respiratory therapy involves the application of oxygen or other gases for purposes of improving, sustaining, or enhancing health. These gases may be of a pure form or they may contain additives in the form of the various medications that may be delivered via the mechanism of breathing.

This form of respiratory therapy may be applied in two fundamental ways depending on the state of consciousness of the subject. When the subject is unconscious, respiratory therapy must be applied without conscious participation. Alternatively, when the subject is conscious and participative, therapy may be applied with the subject's conscious participation. The present invention applies to the latter case, that is, the case wherein there is conscious participation of the care recipient.

It is known that cardiopulmonary efficiency is greatest when the heart and lungs are working in synchrony, this synchrony being identified by the physiological state known as "coherence" of the heart rate variability cycle. In fact, a high degree of coherence of the heart rate variability cycle cannot exist without synchrony between the heart rate variability cycle and the breathing cycle. This synchrony is characterized by the inhalation phase of breathing occurring coincident with increasing heart rate and the exhalation phase of breathing occurring coincident with decreasing heart rate.

While the heart has its own tendency toward rhythm, it is closely coupled to the rhythm of the breathing cycle. The relationship is such that as inhalation occurs, the heartbeat rate tends to increase and as exhalation occurs, the heartbeat rate tends to decrease. It is important to note that while the heartbeat rate and breathing rate influence each other, the relationship is a plesiochronous one, that is, they are independent rhythms that strongly influence but do not directly govern each other. Consequently, it is possible for a human subject to be inhaling while their heart rate is decreasing and exhaling while their heart rate is increasing. This is an undesirable condition and inconsistent with the natural cardio-pulmonary functioning of the body.

Alternatively, it is natural and desirable to inhale while the heart rate is increasing and exhale while the heart rate is decreasing. This is consistent with the natural cardio-pulmonary operation of the body, functions of which are to extract gases from the air, place them into the bloodstream, and circulate them throughout the body where they may be utilized for metabolic processes, the absorption function being maximized when inhalation and increasing heart rate are synchronized. Similarly, the function of exchanging carbon dioxide and other gaseous waste products from the bloodstream and expelling them through the lungs is maximized when exhalation and decreasing heart rate are synchronized.

The present invention takes advantage of the relationship between the breathing cycle and the natural heart rate variability cycle to bring the heart rate variability cycle to the desired state of coherence, and consequently, the

cardio-pulmonary system to its maximal efficiency and effectiveness. In this state of maximal efficiency and effectiveness, respiratory therapy may be applied with the following advantages:

1) optimal transfer and absorption of gases into the bloodstream,
2) optimal circulation of gases throughout the body,
3) optimal exchange of gaseous waste products, that is, carbon dioxide, etc.,
4) consequent increase in therapeutic efficacy,
5) consequent decreases in time of treatment and duration of therapy,
6) consequent reduction in the volume of gases and or medications applied over the course of treatment with consequent reductions in the cost of therapy.

<u>Summary of the Invention</u>

The present invention applies prior inventions including Method and System for Consciously Synchronizing the Breathing Cycle with the Natural Heart Rate Cycle (10/699, 025) and System and Method for Synchronizing the Heart Rate Variability Cycle with the Breathing Cycle (February, 2004) specifying methods and systems for achieving coherence of heart rate variability by either consciously synchronizing the breathing cycle with the heart rate variability cycle or by facilitating synchronization of the heart rate variability cycle with the breathing cycle. Additionally, it applies systems and methods of prior inventions including Method of Presenting Audible and Visual Cues for Synchronizing the Heart Rate Variability Cycle With An External Timing Reference for Purposes of Synchronizing the Heart Rate Variability Cycle with the Breathing Cycle (March 15, 2004), and Method and System Providing A Fundamental Musical Interval for Heart Rate Variability Synchronization (March 23, 2004) to provide audible, visual, and tactile indicators for purposes of indicating to a conscious respiratory therapy recipient, when to inhale and when to exhale, thereby maintaining the state of coherence of the heart rate variability cycle while the recipient undergoes respiratory therapy in the form of breathing therapeutic gases and or gas-borne medications.

A second preferred embodiment of the present invention provides the method and system for regulating the flow of gases during the application of respiratory therapy in accordance with the breathing cycle.

Finally, an instructive method is specified for both respiratory therapy practitioners and care recipients in the application of the preferred embodiments of the present invention.

Brief Description of the Drawing Figures

The accompanying drawing figures incorporated in and forming a part of this specification illustrate several aspects of the invention and together with the description serve to explain the principles of the invention.

FIGURE 1 depicts the application of respiratory therapy while the heart rate is being monitored and the recipient is consciously synchronizing their breathing cycle with their heart rate variability cycle.

FIGURE 2 depicts the application of respiratory therapy while the recipient is synchronizing their breathing cycle to an external timing reference and their heart rate variability is not being monitored.

FIGURE 3 depicts a programmable regulator operating on the basis of the heart rate variability cycle.

FIGURE 4 depicts a programmable regulator operating on the basis of a timing reference.

FIGURE 5 provides a detailed description of the electrically controlled regulator referenced in FIGURES 1 though 4.

FIGURE 6 presents a table describing the operation of the electrically controlled regulator.

Detailed Description of the Preferred Embodiments

The present invention provides a method and system by which respiratory therapy may be optimally applied to conscious recipients by bringing the recipient's heart rate variability cycle into the desired state of coherence, thereby bringing their cardio-pulmonary system into optimal efficiency and effectiveness. This is accomplished in two principal ways. Firstly, by applying

respiratory therapy while monitoring the recipients heart rate variability cycle and instructing the recipient to consciously synchronize their breathing cycle with their heart rate variability cycle per prior invention, Method and System for Consciously Synchronizing the Breathing Cycle with the Natural Heart Rate Variability Cycle (10.699, 025). Secondly, by applying respiratory therapy while instructing the recipient to synchronize their breathing cycle with an external timing reference with a fundamental periodicity of 11.8 seconds per prior invention, System and Method for Synchronizing the Heart Rate Variability Cycle With The Breathing Cycle. The detailed description of preferred embodiments will now commence.

Referring to FIGURE 1, respiratory therapy recipient **101** is in either a seated or reclining position. Gas delivery system **102** typically consists of a tank **103** or supply line **105** from which gas is delivered in the location of the recipient. This may be a portable delivery system or an integral part of a health care physical infrastructure as may be found in a hospital. Tank **103** or supply line **105** are buffered by primary regulator/check valves **104** and **106**, respectively. Gas delivery system **102** may or may not provide the facility for local addition and mixing of other therapeutic gases or medications. Electrically controlled regulator **107** facilitates the automatic control of gas delivery. Cannula **108** is fitted to the recipient and connected to electrically controlled regulator **107**. During therapy, gases flow from tank **103** or supply line **105** through primary regulators **104** or **106**, through electrically controlled regulator **107**, and through cannula **108** to recipient **101**.

Heart rate detector **109** is fitted to recipient **101** such that the heart rate variability cycle can be monitored during the application of respiratory therapy. Heart rate detector **109** is attached to heart rate variability monitor **110** where positive going and negative going phases are discriminated per prior invention Method and System for Consciously Synchronizing the Breathing Cycle with the Natural Heart Rate Cycle (10/699, 025). A positive going phase is the interval between the lowest heart beat rate in beats per second and the highest heart rate in beats per second. A negative going phase is the interval between the highest heart beat rate in beats per second and the lowest heart

beat rate in beats per second. These positive and negative phases are presented to subject **101** via transducer **111** in either audible, visual, or tactile format depending on what form is most applicable to the needs of subject **101**. Subject **101** is instructed to synchronize his inhalation with positive going phases and his exhalation with negative going phases. Per a preferred embodiment of the present invention, a separate output of heart rate variability monitor **110** connects to electrically controlled regulator **107** for the purpose of synchronizing regulator operation with the heart rate variability cycle of the subject. In this way, the subject's breathing cycle is synchronized with their heart rate variability cycle bringing the subjects cardio-pulmonary system into optimal efficiency and effectiveness during which respiratory therapy is applied. Gas flows to the subject during the inhalation phase of the breathing cycle and is stopped during the exhalation phase of the breathing cycle. The function of controlling electrically controlled regulator **107** will be explained in more detail in FIGURE 3.

FIGURE 2 applies prior inventions System and Method for Synchronizing the Heart Rate Variability Cycle With The Breathing Cycle (February 2004), Method of Presenting Audible and Visual Cues for Synchronizing the Breathing Cycle With An External Timing Reference for Purposes of Synchronizing The Heart Rate Variability Cycle With The Breathing Cycle (March 15, 2004), and Method and System Providing A Fundamental Musical Interval for Heart Rate Variability Synchronization (March 23, 2004). In the case of FIGURE 2 and per prior invention, System and Method for Synchronizing the Heart Rate Variability Cycle With The Breathing Cycle (February 2004), the subject synchronizes their breathing cycle with a timing reference signal with a fundamental periodicity of 11.8 seconds. The subject is instructed to inhale on positive going phases of the 11.8 second interval, the positive phase equaling 5.9 seconds, and exhale on negative going phases of the 11.8 second interval, the negative going phase equaling 5.9 seconds. These phases are presented to subject **201** via indicator **210** which may be of an audible, visual, or tactile variety depending on what is appropriate. When the subject follows this method, their heart rate variability cycle synchronizes with their breathing cycle bringing the cardio-pulmonary

system into optimal efficiency and effectiveness during which respiratory therapy is applied. A separate output from timing reference **209** connects to electrically controlled regulator **207** for the purpose of synchronizing regulator operation with the timing reference and thereby synchronizing the operation of electrically controlled regulator **207** with the breathing cycle of the subject. Gas flows to the subject during the inhalation phase of the breathing cycle and is stopped during the exhalation phase of the breathing cycle. The function of controlling electrically controlled regulator **207** will be explained in more detail in FIGURE 4.

FIGURE 3 provides a more in depth discussion of concepts discussed relative to FIGURE 1. FIGURE 3 describes the preferred embodiment of the present invention wherein previously mentioned electrically controlled regulator **107** is controlled. Referring to FIGURE 3, the objective of this control is to open programmable regulator **301** during the inhalation phase of breathing and close programmable regulator **301** during the exhalation phase of breathing thereby reducing the volume of gases and medications and consequent cost by 50%. Gas is delivered to electrically controlled regulator **301** via gas inlet **302**. Gas exits regulator **301** and is delivered to the recipient via gas outlet **303** under control of regulator **301**. The throughput of regulator **301** is controlled by heart rate variability monitor **304** via connector **308**. Per prior invention, Method and System for Consciously Synchronizing the Breathing Cycle with the Natural Heart Rate Variability Cycle (10/699, 025), a function of heart rate variability monitor **304** is to monitor the heart beat rate and detect positive and negative going phases of the heart rate cycle so as to present those phases to the subject for the purpose of synchronizing the breathing cycle with the heart rate variability cycle. Information pertaining to heart rate variability phase is presented via connector **307** to the subject via audible, visual, or tactile indicator **306**. As previously mentioned, per the present invention, a second heart rate variability monitor output **308** is provided for the purpose of synchronizing operation of electrically controlled regulator **301** with the heart rate variability cycle of the subject. Given that the subject's breathing cycle is synchronized with their heart rate variability cycle, per the instruction given the subject, regulator **301** opens during the inhalation phase

of breathing and closes during the exhalation phase of breathing. This function is explained in more detail in FIGURE 3a.

FIGURE 3a provides a graphical representation of heart beat rate as seen by heart rate variability monitor **304** as provided by heart beat detector **305**. Per the present invention, a function of heart rate variability monitor **304** is to discriminate between positive and negative phases of the heart rate variability cycle, the positive phase defined by the interval between peak negative heart beat rate **313** and peak positive heart beat rate **315,** and the negative phase defined by the interval between peak positive heart beat rate **315** and peak negative heart beat rate **316,** for the purpose of controlling electrically controlled regulator **301**. Three periods are critical to realizing the required control. During period 1 **310**, the regulator transitions from being completely closed to being completely open. During period 2 **311**, the regulator transitions from being completely open to being completely closed. During period 3 **312**, the regulator remains closed. In this way, the flow of gas through electrically controlled regulator **301** is synchronized with the inhalation of the subject such that peak flow occurs at mid-inhalation. Note that when a cannula is employed, the subject remains able to inhale regardless of whether or not gas is flowing. Visual indicator **309** is indicative of the degree to which electrically controlled regulator **301** is open and consequently, is indicative of gas flow.

FIGURE 4 provides a more in depth discussion of concepts relative to FIGURE 2. FIGURE 4 describes the preferred embodiment of the present invention wherein previously mentioned electrically controlled regulator **207** is controlled. Again, FIGURE 4 differs from FIGURE 3 in the same way that FIGURE 2 differs from FIGURE 1, that being the absence of heart rate variability monitor and heart beat detector **304** and **305,** respectively, as depicted in FIGURE 3, and the addition of timing reference **404** as depicted in FIGURE 4. As previously mentioned relative to FIGURE 2, FIGURE 4 applies prior inventions, System and Method for Synchronizing the Heart Rate Variability Cycle With The Breathing Cycle (February 2004), Method of Presenting Audible and Visual Cues for Synchronizing the Breathing Cycle

With An External Timing Reference for Purposes of Synchronizing The Heart Rate Variability Cycle With The Breathing Cycle (March 15, 2004), and Method and System Providing A Fundamental Musical Interval for Heart Rate Variability Synchronization (Filed March 23, 2004). In this case, timing reference **404** provides an output **405**, representative of the breathing cycle such that inhalation and exhalation phases can be communicated to the subject via audible, visual, or tactile indicator **406**.

Per the present invention, timing reference **404** provides a second output **407**, for purposes of controlling electrically controlled regulator **401**. This control is essentially the same as that described relative to FIGURE 3, the objective being to synchronize the flow of gas through electrically controlled regulator **401** with the breathing cycle of subject. Timing requirements relative to this function are identical to those of FIGURE 3a. Visual indicator **408** is indicative of the degree to which electrically controlled regulator **401** is open, and consequently, is indicative of gas flow.

FIGURE 5 presents a more detailed view of electrically controlled regulators **301** and **401** which are of identical design. Per FIGURE 5, the primary function of electrically controlled regulator **501** is to synchronize the delivery of gas with the breathing cycle of the recipient. To accomplish this, regulator **501** must open as the inhalation phase begins, achieving maximal flow at mid-inhalation, and begin closing such that it is fully closed at the end of inhalation. It must then remain closed for the duration of exhalation. This function is accomplished by a reciprocating armature **504** that reciprocates under control of the heart rate variability monitor or timing reference **511**. This is accomplished by alternately driving independent coils **505** and **506** which are wound in opposition such that **505** serves to move the armature downward and **506** serves to move the armature upwards. When neither coil is activated springs **507** and **508** counterbalance each other such that the armature rests in the center, maximally opening the channel through which gas flows from inlet **503** to outlet **504**. This is the resting position of the armature when heart rate variability monitor or timing reference **511** is not turned on or not provided.

A more detailed discussion of the cyclic functioning of electrically controlled regulator **501** will now commence. **512**, **513**, **514**, and **515** present the status of reciprocating armature **504** at different moments of one cycle of operation as identified in FIGURE 3a, t=1 **313**, t=2 **314**, t=3 **315**, and p 3 **312**. This functioning is further elucidated in FIGURE 6 table **601** wherein 2 consecutive cycles of operation are described. Referring back to FIGURE 5, at the beginning of cycle 1, as characterized by moment t=1 **313** of FIGURE 3, output A **509** of heart rate variability monitor or timing reference **511** is negative 5 volts, the peak negative output corresponding to the lowest heart beat rate and the end of the exhalation phase of the breathing cycle. This negative 5 volt output actuates coil **505**, driving reciprocating armature **504** to its downward most position **512** closing valve **516**. Therefore at t=1 **313**, valve **516** is fully closed. At t=2 **314**, output A **509** of heart rate variability monitor or timing reference **511** has transitioned from negative 5 volts to 0 volts. It is important to note that while voltages are specified at particular moments, the outputs of heart rate variability monitor or timing reference **511** are analog voltages representing the sinusoidal nature of the heart rate variability and breathing cycles. With this transition, reciprocating armature **504** moves from its downward most position **512** to center position **513**, aligning the hole with channel **502** thereby maximally opening valve **516**. At t=2 **314**, output B **510** of heart rate variability monitor or timing reference **511**, heretofore at 0 volts, begins to transition from 0 volts to positive 5 volts, actuating coil **506** and driving reciprocating armature **504** in the upward direction. As this happens, valve **516** begins to close. At t=3 **315**, output B **510** has reached its peak output of positive 5 volts driving armature **504** to its upward most position per **514**. During the entirety of period 3, p 3 **312**, armature **504** remains in its upward most position **515**, fully closing valve **516**. Visual indicator **517** is indicative of gas flow through valve **516** and varies such that it is brightest when outputs A **509** and B **510** are zero volts. At t=1' **316** this cycle repeats itself in a reverse order. This order is fully described in FIGURE 6 wherein two complete cycles of operation are described. The process outlined in table **601** repeats itself for the duration of the therapy session. This completes the discussion of FIGURES 1-6.

An instructive method is also specified for use by respiratory care practitioners and care recipients. Two different instructive methods are provided depending on which preferred embodiment is being employed, that employing monitoring of the heart rate, or that employing a timing reference.

Instructive Method Employing Heart Rate Monitoring:

1. The care recipient is instructed to assume a comfortable posture and relax as deeply as possible.
2. The care practitioner applies a heart rate monitor to the care recipient.
3. The care practitioner selects the mode of indication that is most suitable to the care recipient.
4. The care practitioner applies a cannula to the care recipient, turns on, and adjusts the supply of gas at the primary regulator.
5. Care recipients are instructed to pay attention to the indicator, inhaling when and for the duration indicated, and exhaling when and for the duration indicated.
6. The care practitioner observes the care recipient and the gas delivery visual indicator to assess the degree of synchronization that is occurring between the recipient's breathing and gas delivery.
7. The care practitioner councils the care recipient in achieving the desirable degree of synchronization.
8. The care practitioner instructs the care recipient to continue breathing in the synchronized manner for the duration of therapy.

Instructive Method Employing A Timing Reference:

1. The care recipient is instructed to assume a comfortable posture and relax as deeply as possible.
2. The care practitioner selects the mode of indication that is most suitable to the care recipient.
3. The care practitioner applies a cannula to the care recipient, turns on, and adjusts the supply of gas at the primary regulator.
4. The care practitioner turns on the timing reference.

5. Care recipients are instructed to pay attention to the indicator, inhaling when and for the duration indicated, and exhaling when and for the duration indicated.
6. The care practitioner observes the care recipient and the gas delivery visual indicator to assess the degree of synchronization that is occurring between breathing of the care recipient and gas delivery.
7. The care practitioner councils the care recipient in achieving the desirable degree of synchronization.
8. The care practitioner instructs the care recipient to continue breathing in the synchronized manner for the duration of therapy.

Those skilled in the art will recognize improvements and modifications to the preferred embodiments of the present invention. All such improvements and modifications are considered within the scope of the concepts disclosed herein and the claims that follow.